



MAR 13 1998

Rec'd 3/26/98

President
Apothecary Preference
307 Placentia Avenue
Newport Beach, California 92663

Dear Sir:

This is in response to your submission¹ of October 21, 1997 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Apothecary Preference is making the following claim, among others, for the products:

Zinc Lozenges

"Scientific studies show that zinc provides nutritional support for the throat, especially during the cold flu season."

Defense Formula

"The Defense Formula supplies the powerful herbs Echinacea and Golden Seal plus Vitamin C and other important vitamins, minerals and nutrients clinically shown to support the body's natural defense system during the cold and flu season. Supports the body's natural defense system."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent, treat or mitigate disease, namely the common cold and influenza. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

¹Submission made on your behalf by Emord & Associates, P.C., 1050 Seventeenth Street, N.W., Suite 600, Washington, D.C. 20036.

975-0163

LET 138

Page 2 - President, Apothecary Preference

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, KCarson)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:3/12/98
Init:GCF-1:LNickerson:3/12/98
f/t:HFS-456:rjm:3/13/98:docname:55367.adv:disc26

EMORD & ASSOCIATES, P.C.

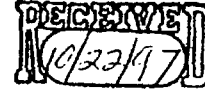
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October 21, 1997

VIA UPS NEXT DAY AIR

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Fulfillment of Reporting Obligation Under 21 U.S.C. § 343(r)

Dear Dr. Yetley:

Apothecary Preference,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Apothecary Preference retains scientific documentation supporting the statements.

1. Supplement Brand Name

Memory Formula

Supplement Ingredients

Phosphatidyl Choline
Ginko Biloba
Niacinamide
PABA
Zinc (Chelate)
Lecithin
L-Glutamine
Gotu Kola

¹ The address for Apothecary Preference is 307 Placentia Avenue, Newport Beach, California 92663.

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Acetyl Choline
Vitamin B-6
L-Tyrosine

Text of Statements of Nutritional Support

The Memory Formula provides Ginko Biloba and Gotu Kola with other important vitamins, minerals, and amino acids which scientific studies suggest support mental alertness and memory function.

Promotes mental alertness and brain function.

2. Supplement Brand Name

Zinc Lozenges

Supplement Ingredients

Zinc Aspartate

Text of Statements of Nutritional Support

Scientific studies show that zinc provides nutritional support for the throat, especially during the cold flu season.

Nutritional support for the body's defense system

3. Supplement Brand Name

Antioxidant Formula

Supplement Ingredients

Vitamin C (calcium ascorbate)
Vitamin E (d-alpha tocopherol)
Vitamin A (beta-carotene)
Selenium (methionine)
Zinc (protein chelate)
Grape Seed extract
Citrus bioflavonoids
Superoxide dismutase (SOD)
Lutein (Spinach)
CoQ10

Text of Statements of Nutritional Support

The Antioxidant Formula is a complete system of potent antioxidants which provide ultimate protection from free radicals.

Scientific research suggests that antioxidants neutralize free radicals the highly reactive oxygen molecules that have been shown to damage cells and tissues.

4. Supplement Brand Name

Defense Formula

Supplement Ingredients

Echinacea (root)
Golden seal (root)
Vitamin C (calcium ascorbate)
Bioflavonoid complex
Vitamin A (acetate)
Vitamin A (beta-carotene)
Zinc (protein chelate)
Vitamin B-6

Text of Statements of Nutritional Support

The Defense Formula supplies the powerful herbs Echinacea and Golden Seal plus Vitamin C and other important vitamins, minerals and nutrients clinically shown to support the body's natural defense system during the cold and flu season.

Supports the body's natural defense system.

5. Supplement Brand Name

DHEA

Supplement Ingredients

DHEA

Text of Statements of Nutritional Support

Numerous studies have also shown that DHEA supports many physiological processes.

6. Supplement Brand Name

Osteo Formula

Supplement Ingredients